

Department of Commerce · National Oceanic & Atmospheric Administration · National Marine Fisheries Service

<i>NATIONAL MARINE FISHERIES SERVICE POLICY DIRECTIVE 04-112</i>	
<i>August 21, 2015</i>	
<i>Science and Technology</i>	
<i>NMFS Animal Care and Use Policy</i>	
NOTICE: This publication is available at: http://www.nmfs.noaa.gov/op/pds/	
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<i>SUMMARY OF REVISIONS:</i> Changes in IACUC operations, reporting structure, and training requirements	

Introduction

National Oceanic and Atmospheric Administration's (NOAA) National Marine Fisheries Service (NMFS) conducts and supports research activities involving live marine mammals and turtles. In 2007, the NMFS Science Board established a Task Team to develop a policy and an implementation plan for NMFS Animal Care and Use Committees in accordance with the Animal Welfare Act (AWA) and its implementing regulations, the U.S. Government Principles (USGP) for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, Office of Science and Technology Policy (OSTP) CFR May 20, 1985, Vol.50, No. 97, and the Marine Mammal Protection Act (MMPA) to assure that research methods used by NMFS or NMFS-funded researchers on live marine mammals and sea turtles constitute humane treatment of those animals. This current document is an update to the original directive from July 2010 based on recommendations from the 3 regional Institutional Animal Use and Care Committee (IACUC) Chairs, Office of Science and Technology (F/ST), and the Office of Protected Resources (F/PR).

Animal Welfare Act (AWA) 7 U.S.C. §2131 et seq.

The AWA charges the Secretary of Agriculture with promulgating regulations and standards for the humane handling, care, treatment, and transportation of animals by dealers, research facilities, and exhibitors. For research facilities, requirements include annual reporting and establishing an IACUC to review protocols and assure compliance with AWA. The AWA states

that “Each Committee shall be appointed by the Chief Executive Officer of each such research facility and shall be composed of a minimum of three members. Members shall possess sufficient ability to assess animal care, treatment, and practices in experimental research as determined by the needs of the research facility and shall represent society’s concerns regarding the welfare of animal subjects used at such facility.” These requirements apply to federal and non-federal research facilities.

The AWA exempts “field studies” defined as “*any study done on free-living wild animals in their natural habitat, which does not involve an invasive procedure, and which does not harm or materially alter the behavior of the animals under study*” from full review and approval by an animal care and use committee. The NMFS IACUC Chair may make determinations that projects that meet the definition of field study are exempt from further IACUC review. Marine mammal and sea turtle stranding response, rescue, rehabilitation, and post-release monitoring are exempt from IACUC reviews. However, any invasive scientific research study involving a stranded or rehabilitated marine mammal or sea turtle will require IACUC review.

U.S. Government Principles (USGP) for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training

In 1985, these principles were developed by the Interagency Research Animal Committee. Specifically, whenever U.S. Government agencies perform or sponsor testing, research, or training procedures, the responsible Institutional Official (IO) shall ensure adherence to these (I-IX) [principles](#). A copy of these principles is attached to the accompanying procedural directive as an appendix. Further guidance on these principles can be obtained from the [Guide for the Care and Use of Laboratory Animals](#) prepared by the Institute for Laboratory Animal Research, National Academy of Sciences. For research on live sea turtles, the IACUCs will review and evaluate ‘humaneness’ of actions on the basis of the adherence to USGP I-IX and the Guide for the Care and Use of Laboratory Animals, defined as “*humane care means those actions taken to ensure that laboratory animals are treated according to high ethical and scientific standards. Implementation of a humane care program, and creation of a laboratory environment in which humane care and respect for animals are valued and encouraged, underlies the core requirements of the Guide and the system of self-regulation it supports.*”

Marine Mammal Protection Act (MMPA)

NMFS IACUC reviews are required for all animal capture, handling and invasive research conducted on wild marine mammals by NMFS personnel. There are no definitions of “humane” in the AWA and AWAR and consistent with the original 2010 IACUC policy and procedural directive, NMFS IACUCs will continue to use the MMPA definition of “humane” in MMPA Section 3. Definitions 16 U.S.C. 1362 to evaluate humaneness of the research conducted on wild marine mammals under the MMPA.

Objective

The Agency will carry out the requirements of the AWA and its implementing regulations in 9 C.F.R. §1.1 *et seq.* (AWAR). This policy will apply to all NMFS research on live marine mammals and sea turtles conducted, authorized, or funded by NMFS, and includes Principal Investigators (PI) from the science centers, headquarters or regional offices, and Co-Investigators (CI) conducting research activities including fisheries observer programs.

Three regional IACUCs have been established to review animal use in research and recovery programs implemented by the NMFS science centers, regional offices, F/ST, and Office of Protected Resources (F/PR). The three regional NMFS IACUCs are a) *Northeast/Southeast science centers' IACUC*, b) *Pacific Islands/Southwest science centers' IACUC*, and c) *Northwest/Alaska science centers' IACUC*.

The primary function of the regional NMFS IACUCs will be to review Assurance of Animal Care and Use Forms (AAC&UF), with the goal of assessing and assuring that all research procedures involving live marine mammals and sea turtles are humane. The humaneness determination is based on Section 16 U.S.C. 1362 of the MMPA as the “*method of taking, import, export, or other activity which involves the least possible degree of pain and suffering practicable to the animal involved*” (see Glossary), and the principles I-IX under USGP and AWAR goal: *Procedures involving animals will avoid or minimize discomfort, distress and pain to the animals* 9 CFR Part 2, subpart C, Section 2.31(d)(i).

Once the AAC&UF is approved, it is considered an “approved protocol” The IACUC prepares a Letter of Assurance of compliance with AWA, the USGP, and NMFS IACUC policy that is valid for a period of five years and forwards it to the PI and IO.

PI or CIs from F/ST, F/PR, or other NMFS headquarters or regional office will submit AAC&UF forms to the regional IACUC depending on study area.

This approach fosters collaboration and consistency among the regional IACUCs. The Committees will follow the procedures outlined in the Procedural Directive 04-0114-01 entitled *NMFS Animal Care and Use Committee Standards*. This approach also provides Letters of Assurance that research protocols involving live marine mammals and sea turtles are being conducted in a humane fashion and assists F/PR in issuance of MMPA and ESA marine mammal research permits to NMFS scientists.

Authorities and Responsibilities

In accordance with the AWAR in 9 C.F.R. §2.37, the science center Director/s will be the IO for NMFS IACUCs responsible for all research involving live marine mammals and sea turtles conducted or supported by the agency and assures compliance with AWA, AWAR, and USGP.

National direction and consistency will be established and maintained by F/ST in

coordination and consultation with the Directors of the six science centers and associated IACUC Chairs, and relevant headquarters and regional offices.

The three regional NMFS IACUCs will review Assurance of Animal Care and Use Form (AAC & UF) or modifications to protocols. Each regional committee will represent more than one NMFS region and will have the same composition, additional duties, and responsibilities required of non-federal research facilities under 9 C.F.R. §2.31, with two exceptions:

- The committee will report non-compliance with approved protocols or animal holding deficiencies to the IO overseeing the research rather than to the U.S. Department of Agriculture Animal and Plant Health Inspection Service (APHIS);
- The IO overseeing the research will be responsible for all research activity as approved by the regional NMFS IACUC and for the granting of all exceptions to approved protocols.

Measuring Effectiveness

This Policy will be reviewed and updated if necessary in accordance with the [NMFS Policy Directive System](#).

Training

NMFS PIs should have a basic understanding of AWA and forms to be completed for IACUC reviews. A set of training modules is available through regional IACUCs. PIs and CIs should certify that they have read the relevant modules as part of the AAC&UF. In general, each IACUC committee member should take or have taken the equivalent of an IACUC 101 course during the beginning of their tenure and take additional training as available and appropriate.

Signed

/S/ August 7, 2015

Eileen Sobeck

Date

Assistant Administrator for Fisheries